This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 16-R-0029
CUSTOMER NUMBER: 55

FORM APPROVED
OMB NO. 0579-0036

Boehringer Ingelheim Pharmaceuticals Inc
900 Ridgebury Road, Po Box 368
Ridgefield, CT 06877

(b)(6) and (b)(7)(c)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessarv or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	21	77	32	33	142
5. Cats	0	0	0	0	0
6. Guinea Pigs	29	100	133	220	453
7. Hamsters	0	0	392	1198	1590
8. Rabbits	0	0	0	0	0
9. Non-human Primates	81	67	29	42	138
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6) and (b)(7)(c)

DATE SIGNED 11/20/07

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

(b)(6) and (b)(7)(c)

E4

33 dogs assigned to Column E of this report were used in non-clinical laboratory studies to evaluate (b) (4) of test compounds in accordance to Food and Drug Administration requirements under Good Laboratory Practice regulations 21 CFR 58.
These animals received a high dose of a test agent by oral gavage and experienced clinical signs of emesis and diarrhea. The dogs were given supportive therapy, including fluid therapy, but were not given other drugs such as analgesics that might cause reversal of (b) (4) effects of the test article or induce their own inherent (b) (4) or drug-drug interactions.

E6

220 guinea pigs assigned to Column E of this report were used in non-clinical laboratory studies to (b) (4) to a specific trace component in accordance to Food and Drug Administration requirements under Good Laboratory Practice regulations 21 CFR 58. The animals were (b) (4) (b) (4) through administration of that agent (b) (4) followed (b) (4) The (b) (4) was expressed as a degree of (b) (4) in the guinea pigs. The (b) (4) measured at the (b) (4) (b) (4). No analgesics were administered during the (b) (4) time period because those agents had the potential (b) (4) which was the end point that was to be measured and therefore could interfere with the accurate interpretation of the properties of (b) (4).

E7

1198 hamsters assigned to Column E of this report underwent [redacted] surgical procedures for the purpose of creating [redacted] models for use in evaluating and identifying compounds that may be beneficial in treatment of humans. Although the animals received peri-operative analgesics and anesthesia, they did not receive continuous analgesics during the remainder of the study because the side effects of such drugs could [redacted] which could result in increased mortality of the animals.

E9

15 macaque monkeys assigned to Column E of this report were used as a model of (b) (4) n which they were (b) (4), dosed with test compound by intravenous route and then skin (b) (4) d with (b) (4). Although (b) (4) was minimized, the animals experienced (b) (4). Analgesics were not administered during the post-challenge period to avoid interference with the development of the (b) (4).

27 macaque monkeys assigned to Column E of this report were used in non-clinical laboratory studies to evaluate (b) (4) of test articles in accordance to the Food and Drug Administration requirements under Good Laboratory Practice regulations, 21 CFR 58. The animals were used (b) (4) studies to determine potential (b) (4) (b) (4) of the test article that was administered by either oral gavage or intravenous route. Following (b) (4), the animals developed clinical signs of emesis and diarrhea. The animals were given supportive therapy, including fluid therapy and temporary discontinuance of test article until the animals were stabilized, but were not given other drugs such as analgesics that might cause reversal of (b) (4) of the test article or induce their own inherent (b) (4) or drug-drug interactions.